UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Revised BEAD Review of "The Aventis CropScience StarLink Quality Plan for Corn Dry Mills".

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Summary

I used two different methodologies to validate the four Cry9C concentration scenarios presented in Volume 7 of the latest Aventis CropScience submission. Using the first method, which assumes complete mixing of StarLink and conventional corn at the state level, I concluded that Aventis Scenario #2 was the most likely of the four scenarios proposed by Aventis. I predicted slightly higher average residues of the Cry9C protein (8 ppb) than those predicted by Aventis in scenario 2 (6 ppb).

Using the second method, which predicts a distribution based on the incidence of positive (5%) and negative (95%) detects in the monitoring program, I concluded that the actual concentration of Starlink in the food corn supply is closer to Aventis scenario #4. This methodology predicts lower average residues of the Cry9C protein (0.34 ppb) than those predicted by Aventis in scenario 4 (2.1 ppb). The low incidence of positive detects in the monitoring program may have occurred because the Cry9C concentrations in buffer corn (which currently represents 99% of the unaccounted StarLink corn) contains significantly lower Cry9C concentrations than grain from StarLink fields (0.15 ppm vs 15 ppm). Another explanation for the lower levels predicted by this method is that most of the unaccounted StarLink corn may

have already moved into food processing prior to the Lateral Strip Flow monitoring effort. In my opinion, Aventis would have to formally submit the results of their monitoring program before the Agency could seriously consider the estimates predicted in the second method.

Background

The following represents my review of the four Cry9C concentration scenarios presented in Volume 7 of the latest Aventis CropScience submission entitled "The Aventis CropScience StarLink Quality Plan for Corn Dry Mills"(completed on April 12, 2001). In light of the new information presented in this volume, I have revised the Starlink Concentration Distribution Table included in my November 14, 2000 StarLink memorandum (Table 1) (Brassard, 2000).

The key piece of information in Volume 7 that precipitated this revision is the observation that strip testing of grain revealed that fewer than 5 percent of the truckloads of grain had detectable (0.125% or 20 ppb) levels of Starlink corn. No information was given in Volume 7 regarding the robustness of the sampling or regions involved in the sampling. If one assumes that the sampling was representative of all regions, these results suggest that there may be: 1) less unaccounted StarLink corn than originally assumed (presumably because of better compliance with the label); 2) that the distribution of unaccounted Starlink corn is less random than originally assumed (i.e. heavily concentrated in a few elevators); 3) that the unaccounted for StarLink corn was blended with more conventional corn that had moved off-farm than originally assumed (e.g 67% rather than 33%); 4) most of the unaccounted for Starlink corn had already moved into food processing prior to monitoring or 5) that the Cry9C concentrations in buffer corn, which represents 99% of the unaccounted StarLink corn (or 3.65 out of 3.68 million bushels)(Aventis, 2001b), is significantly lower than in pure StarLink corn (Lauer, Ireland, and Wilson, 2001). This last observation is significant because my November 14, 2000 StarLink memorandum assumed that about 16% of the unaccounted corn was buffer corn.

In this analysis, I assumed that all corn destined for food processing would be tested for the presence of StarLink and that trucks testing positively for StarLink would be diverted for animal consumption. This may not actually be the case since lateral strip flow testing is voluntary among food processors. To date 2.2 million test kits have been distributed to food processors (Barbara Henry, 2001 personal communication). This is enough to test 733,000 truckloads of grain (out of the 1.3 million truckloads of grain delivered to the food processing industry annually).

I used two different methods to estimate the residue distribution of StarLink in the food corn supply. The first method assumes complete mixing of corn at the state level. The second method predicts a distribution based on the incidence of positive and negative detects in the monitoring program.

Method 1: Assume complete mixing of corn at the state level

The distribution predicted by this method assumes complete mixing of all unaccounted StarLink corn and conventional corn at the state level. It also assumes that the unaccounted StarLink corn is as likely to be marketed to food processors as conventional corn. Other assumptions include:

- all 3.68 million bushels of unaccounted StarLink corn is commingled with the 67% of conventional corn which has moved off farm by July 2001.

- the Cry9C concentrations in unaccounted StarLink corn contains 15 ppm Cry9C. This is probably an overestimate since buffer corn, which currently represents 99% of the unaccounted StarLink corn, contains significantly lower Cry9C concentrations than grain from StarLink fields (0.15 ppm vs 15 ppm)

The sensitivity of the Lateral Strip Flow test method is 1 kernel in 800 or 0.125 percent. Taking three 800 kernel samples, as recommended in the testing protocol, assures a 95 percent certainty that there is less than 0.125 percent Starlink corn if all samples are negative. However, 5 percent of the trucks with 0.125 percent or more StarLink grain will be false negatives and these represent the top 5 percent of the revised likely distribution. I used a probabilistic procedure to determine the concentration of StarLink corn at the 99.9th percentile. As shown in Table 1, about one truck in 50 (2% of the false negative population) will pass the sampling procedure with a 0.162% concentration (or one kernel in 615) of StarLink corn and result in a false negative[1] . Multiplying the frequency of false negatives (5%) times the frequency of false negative samples containing 0.162 percent Starlink corn (2%) yields a frequency of 0.1 percent, which represents the 99.9th percentile of the distribution in the revised likely column of Table 2. This methodology assumes a random distribution of the StarLink kernels in the truck and that trucks testing positively for StarLink are diverted to animal feed. As stated previously, this may not actually be the case since lateral strip flow testing is voluntary among food processors.

Another change in the table was necessitated by an observation, in the December 1, 2000 StarLink SAP report, that there are 150 million bushels of white corn and contracted hard endosperm corn where little or no mixing will occur. These represents about 11.5% of the US food corn supply and should probably be portrayed as zero's in the bottom 10% of my distribution (assuming the other 1.5% was minimally mixed). Accordingly, I revised the residue distribution table to incorporate this recommendation.

This revised concentration distribution (Table 1, column 4) suggests that **Aventis Scenario #2** (on pages 11 and 12 of Volume 7) is the most likely of the four scenarios proposed by Aventis. I predict slightly higher average residues of the Cry9C protein (8 ppb) than those predicted by Aventis in scenario 2 (6 ppb). These averages are based on the assumption that a blend of 0.125 percent StarLink corn contains 20 ppb Cry9C protein. I disagree, however, with the concept of averaging residues within this distribution because most of the variability is driven by the different percentages of Starlink corn planted and accounted for in each state and because there is no evidence of significant blending of corn from different regions of the country. Refer to page 2 of my November 14, 2000 memorandum for a detailed discussion of corn grain blending practices. Additionally the risk from Starlink exposures is considered to be an acute risk and Agency policy for acute risk is to use the 99.9th percentile of exposure in the risk assessment. Note that my predicted concentration of 0.289% or 46 ppb for the 99.9th percentile would apply to only one

[1] The probability of positive detects for different concentrations of StarLink corn was calculated using the following formula: $1-[(n-1)/n]^{2400}$ where n = the number of conventional kernels per starlink kernel.

corn containing food item consumed in a single meal (or in a single day). Other corn containing food items consumed on the same day (or in the same meal) would contain different concentrations from other points in the residue distribution. In actual practice, an entire day's consumption of corn containing food products would contain less than 46 ppb because of dilution from other corn containing products with lesser concentrations.

Method 2: Predict a distribution based on the incidence of positive and negative detects in the Aventis monitoring program.

Aventis states in Volume 7 that strip testing of grain (in trucks entering food processing facilities) revealed that fewer than 5 percent of the truckloads of grain had detectable (0.125% or 20 ppb) levels of Starlink corn. Given the sensitivity of the Lateral Strip Flow test method (1 kernel in 800 or 0.125 percent) and the number of kernels sampled (3 samples of 800 kernels or 2400 kernels), one would have expected positive samples in 70 percent of the samples if the trucks had an average concentration of 8 ppb (Table 1) as predicted in method one. This difference between the predicted positive sample rate and the actual rate suggests that the methodology in Method 1 may overestimate the amount of Starlink in the food corn supply. In fact, you could only achieve a 5 percent positive sample rate if you had an average concentration of 0.34 ppb StarLink corn (Table 1). This value suggests that the actual concentration of Starlink in the food corn supply is closer to **Aventis scenario #4** (which predicts average concentrations of 2 ppb). Even the distribution in Aventis scenario #4 appears more concentrated than may actually be the case since it results in a positive detect rate of 16.5 percent (Table a).

Table a. Predicted Number of Positive samples which would Result from the StarLink Distribution Portrayed in Aventis Scenario 4.

Truck #	Number of samples	Average Cry9C concentration	Rate of positive samples*	Number of positive samples
1-20	20	0 ppb	0%	0
21-39	19	1 ppb	14%	2.66
40-50	11	8 ppb	70%	5.6
Total	50	--	--	8.26
Average	--	2.14 ppb	16.5%	--

* from table 1

No information was given in Volume 7 regarding the robustness of the sampling, the time period, or the regions involved in the sampling. I suspect that most of the unaccounted for Starlink corn had already moved into food processing prior to the Lateral Strip Flow monitoring effort. If this is the case, then the residue concentrations portrayed in the previous method (#1) would appropriately characterize exposure from grain entering the food processing stream prior to the initiation of the monitoring program. In my opinion, Aventis would have to formally

submit the results of their monitoring program before the Agency could seriously consider the estimates predicted in the second method.

Another explanation for the lower levels predicted by this method is that the Cry9C concentrations in buffer corn (which represents 99% of the unaccounted StarLink corn (3.65 out of 3.68 million bushels)(Aventis, 2001b)) is significantly lower than in pure StarLink corn. Outcrossing studies in buffer fields have shown that hybridization (from StarLink pollen) only occurred in 0.9 to 1.75 percent of the kernels (Lauer, Ireland, and Wilson, 2001). Additionally, since much of the protein in a corn kernel comes from the female parent, Cry9C levels in buffer corn are likely to be less than those found in StarLink corn kernels (Wozniak, 2001). Based on these observations, I estimate that corn grain from buffer fields contains Cry9C concentrations of 0.15 ppm (about 1 percent of the concentration found in grain from StarLink fields).

References

Aventis. 2001a. "The Aventis CropScience StarLink Quality √ Plan for Corn Dry Mills". Volume 7 of 7. Study ID B003273 Aventis CropScience, Research Triangle Park, NC 27709.

Aventis. 2001b. "StarLink Corn Containment Program". Volume 6 of 7. Study ID B003273 Aventis CropScience, Research Triangle Park, NC 27709.

Brassard, D.W. 2000. Draft BEAD Review of Novigen's Safety Assessment of StarLink. Internal Memorandum. Biological and Economic Analysis Division, Office of Pesticide Programs, Environmental Protection Agency, Washington DC 20460, 11 pp.

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Wozniak, C.A. 2000. Cross-pollination of maize in associated buffer zones surrounding StarLink™ Cry9C fields. Internal Memorandum. Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Environmental Protection Agency, Washington DC 20460, 11 pp.

Table 1. Probability of Obtaining Positive and Negative Sampling Outcomes for Various Concentrations of StarLink Containing Corn Grain Shipments[1].

Concentration in corn grain Sample			Probability of Obtaining Indicated Result[2]	
ppb Cry9C	percent StarLink corn	Kernel Ratio (1:N)	Negative detect	Positive detect
46	0.287	348	0.1%	99.9%
31	0.192	522	1%	99%
26	0.162	615	2%	98%
23	0.145	685	3%	97%
20	0.125	800	5%	95%
10	0.0625	1600	22%	78%
9	0.0562	1778	26%	74%
8	0.05	2000	30%	70%
7	0.04375	2286	35%	65%
6	0.0375	2667	41%	59%
5	0.0313	3200	47%	53%
4	0.025	4000	55%	45%
3	0.0188	5333	64%	36%
2	0.0125	8000	74%	26%
1	0.00625	16000	86%	14%
0.5	0.00313	32000	93%	7%
0.34	0.00213	47059	95%	5%
0.3	0.00188	53333	95.6%	4.6%
0.25	0.00156	64000	96%	4%
0.2	0.00125	80000	97%	3%
0.13	0.00081	123077	98%	2%
0.1	0.00063	160000	98.5%	1.5%
0.05	0.00031	320000	99.25%	0.75%

1/ Assumes the use of lateral strip flow testing with a sensitivity of 0.125% or 1/800 StarLink kernels and a sample size of 2400 kernels.

2/ The probability of negative detects for different concentrations of StarLink corn is calculated using the following formula: $[(n-1)/n]^{2400}$ where n = the number of conventional kernels per starlink kernel. The probability of positive detects was calculated using the formula: $1- [(n-1)/n]^{2400}$

Table 2.